REMARKS

Upon entry of the amendment, claims 7 and 10 to 13 are pending. Claim 7 is amended.

No new matter is added. The specification supports the amendment to claim 7, such as on page 9. Further, claim 7 is amended to correct a minor typographical error. Entry of the Amendment is respectfully requested.

I. Claim Rejections – 35 U.S.C. § 112

Claims 7 and 10 to 13 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement (new matter).

Referring to page 3 of the Office Action, the Examiner asserts the claims lack literal written support for "a dissolution rate in 0.1 N HCl at 37° C of about 90 % in 30 minutes." In an effort to advance the prosecution, claim 7 is amended to address the issues raised by the Examiner. Claim 7 presently recites "a dissolution rate in 0.1 N HCl at 37° C of about 89 % in 30 minutes."

II. Claim Rejections – 35 U.S.C. § 103

Claims 7 and 10 to 13 remain rejected under 35 U.S.C. § 103, based on U.S. Published Application No. 2004/0048931 to Heacock, *et al.* ("Heacock '931") in view of U.S. Published Application No. 2003/0022940 to Corvari, *et al.* ("Corvari '940") and Rudnic, *et al.*, "Oral Solid Dosage Forms," *Remington's Pharmaceutical Sciences* 1633-1637 (18th. ed. 1990) ("Rudnic").

Applicants respectfully traverse this rejection.

The Examiner contends that a person of ordinary skill in the art would have modified the composition disclosed in Heacock '931 in accordance with the teachings in Corvari '940 and Rudnic. Referring to pages 7 to 8 of the Office Action, the Examiner concedes that Heacock '931 does not teach a modafinil composition comprising colloidal silicon dioxide, crospovidone, and povidone. The Examiner looks to Corvari '940 and Rudnic to find these excipients. Rudnic is relied upon for teaching colloidal silicon dioxide. Corvari '940 is relied upon for teaching crospovidone and povidone. Referring to page 8 of the Office Action, the Examiner asserts that

a person of ordinary skill in the art would have been motivated to make the proposed modification, because both Heacock '931 and Corvari '940 teach that the formulations thereof have properties similar to those of PROVIGIL® and Rudnic teaches that colloidal silicon dioxide is a glidant.

No reason has been identified as to why a person of ordinary skill in the art would have added colloidal silicon dioxide to the composition disclosed in Heacock '931 to arrive at the claimed invention. The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason why the claimed invention would have been obvious. MPEP § 2143. In the present case, Corvari '940 teaches a broad range of possible excipients that may be used in the composition thereof. Corvari '940, para. [0020]. More specifically, Corvari '940 teaches that examples of the excipients thereof "commonly include fillers or diluents, binders, disintegrants, lubricants, antiadherents, glidants, wetting and surface active agents, colors and pigments, flavoring agents, sweeteners, adsorbents, and taste maskers." *Id.* No reason has been identified as to why a person of ordinary skill in the art would have selected the glidant disclosed in Corvari '940 over the other excipient examples listed therein. To the extent that Corvari '940 teaches selecting a listed excipient, Corvari '940 teaches that a preferred embodiment includes two diluents, two disintegrants, a binder, and a lubricant, but does not teach including the glidant. Corvari '940, paras. [0026] to [0029]. Rudnic is not directly relevant to Heacock '931, as Rudnic is relied upon for teaching a species of the glidant disclosed in Corvari '940. In this regard, no reason has been identified as to why a person of ordinary skill in the art would have added colloidal silicon dioxide to the composition disclosed in Heacock '931.

Further, Corvari '940 and Heacock '931 in combination with Heacock '931, do not render the claimed invention obvious. Heacock '931 does not teach or suggest providing at least 15 % of the cumulative total of modafinil particles to have a diameter of more than about 200 μ. Heacock '931 instead teaches a broad range of particle diameters. In the event that a reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this is not sufficient by itself to establish a *prima facie* case of obviousness. MPEP §§ 2144.05 and 2144.08 (II)(a)(4). Paragraphs [0029] to [0031] of Heacock '931 teach that modafinil lots may be separated into small particle discrete lots, large particle discrete lots, and very large discrete lots. Paragraphs [0029] to [0031] of Heacock '931 also teach several

ranges for each of the small particle lots, large particle lots, and very large particle lots. In this regard, Heacock '931 teaches a broad range of particle diameters that encompasses a very large number of possible distinct compositions.

Heacock '931 teaches that by appropriately blending small, large, and optionally very large particles, the dissolution profile of the blended lots can be made to simulate the dissolution profile of the modafinil composition in which greater than or equal to 95 % of the particles in the effective amount are small particles, i.e., less than about 200 microns. Heacock '931, para. [0038]. Heacock '931 also teaches that not all combinations of small, large, and very large particles will exhibit a dissolution profile similar to PROVIGIL® and bioequivalence to PROVIGIL®. Heacock '931, para. [0064]. Heacock '931 also teaches that routine experimentation will be desirable to determine the optimum particle size makeup and proportions. *Id.* This disclosure teaches the desirable goals of mixing certain discrete lots, but does not specify a reason for selecting one particle diameter over another particle diameter or a reason for selecting a certain amount of one discrete lot. The disclosure that routine experimentation leads to a certain dissolution profile or bioequivalency does not teach which particle size or amount is desirable over another particle size or amount. Reference to "routine testing" or "routine experimentation" is disfavored. *See, e.g., In re Yates*, 663 F.2d 1054 (C.C.P.A. 1981). It follows that Heacock '931 does not provide a reason for the selection of at least 15 % of the cumulative total of modafinil particles to have a diameter of more than about 200 μ.

In view of the above remarks, applicants believe the pending application is in condition for allowance. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Dated: November 24, 2008

/S. Maurice Valla/
S. Maurice Valla
Registration No.: 43,966

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439